510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k061056

B. Purpose for Submission:
New Devices

C. Measurand:
Protein analytes: ASO, Complement C3, Complement C4, CRP, Ferritin, IgA, IgG, IgM, Prealbumin, Transferrin, Haptoglobin

D. Type of Test:
Calibrators

E. Applicant:
Randox Laboratories Ltd.

F. Proprietary and Established Names:
Randox Liquid Protein Calibrators (For Neat Sample Assays)

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1150, Calibrator
2. Classification:
   Class II
3. Product code:
   JIX, Calibrator, Multi-Analyte Mixture
4. Panel:
   Chemistry 75

H. Intended Use:

1. Intended use(s):
   Liquid Protein Calibrators are intended for in vitro diagnostic use in the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, and Transferrin assays on Clinical Chemistry and Immunoassay systems, Abbott Spectrum, Abbott Aeroset, Abbott Architect *i*2000, Architect *i*2000sr, Ace analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, AU800, AU600, AU400, AU2700, AU5400, Selectra Vitalab, Synchron CX4, Synchron CX5, Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira Plus systems.
2. Indication(s) for use:
   The Randox Laboratories Limited Liquid Protein Calibrator (for neat sample assays) is derived from normal human serum obtained from volunteer donors. It has been developed for the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, IgA, IgG, IgM, Prealbumin, Transferrin and Haptoglobin assays (all neat sample assays).
   Assignment was performed at Randox Laboratories by immunoturbidimetry with reference to International Reference Material CRM 470. The constituent

concentrations of these Calibrators are present at levels 1, 2, 3, 4 and 5.

This calibrator can be used on Abbott Spectrum, Abbott Aeroset, Abbott Architect *i*2000 and Architect *i*2000sr, Ace analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, Olympus AU800, AU600, AU400, AU2700, AU5400, Selectra Vitalab, Synchron CX4, Synchron CX5, Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira Plus systems.

The Randox Laboratories Limited Liquid Protein Calibrators, should only be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

For in vitro diagnostic use.

3. Special conditions for use statement(s):
   For prescription use only.
4. Special instrument requirements:
   Abbott Spectrum, Abbott Aeroset, Abbott Architect *i*2000 and Architect *i*2000sr, Ace analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, Olympus AU800, AU600, AU400, AU2700, AU5400, Selectra Vitalab, Synchron CX4, Synchron CX5, Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira Plus systems.

I. Device Description:

The liquid protein calibrators are supplied at 5 levels: 1, 2, 3, and 5. Target values are supplied for the following analytes in Calibrator 1, 2, 3, and 5: Complement C3, Complement C4, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, and Transferrin. Target values are supplied for the following analytes in Calibrator 4: ASO, Complement C3, Complement C4, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, and Transferrin.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Specific Protein Reference Serum
   Randox Liquid Protein Calibrator
2. Predicate 510(k) number:
   k033791 (Haptoglobin, IgA, IgG, IgM, Transferrin, C3, C4)
   k031608 (IgA, IgG, IgM, ASO, Ferritin, Prealbumin, CRP, C3, C4)
3. Comparison with predicate:

Similarities		
Item	New Device	Predicate Device
Calibrator material source	Human serum	Same

Differences		
Item	New Device	Predicate
Indication for Use	The Randox Laboratories Limited Liquid Protein Calibrators (for neat sample assays) is derived from normal human serum obtained from volunteer donors. It has been developed for the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, IgA, IgG, IgM, Prealbumin, Transferrin and Haptoglobin assays (all neat sample assays). Assignment was performed at Randox Laboratories by immunoturbidimetry with reference to International Reference Material CRM 470. The constituent concentrations of these Calibrators are present at levels 1, 2, 3, 4 and 5. This calibrator can be used on Abbott Spectrum, Abbott aeroset, Abbott Architect *i*2000, Abbott Architect *i*2000sr, Ace analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, Olympus AU800, AU600, AU400, AU2700, AU5400, Selectra Vitalab,	Same Indication for Use, except for the equipment listings: (1) Bayer Predicate Device: For calibration of the ADVIA® Chemistry Systems, Technicon RA-500®, Technicon RA-1000®, Technicon® RA-XT™, Technicon RA-2000®, and opeRA® chemistry system specific protein methods. (2) Randox Predicate Device: For Bayer ADVIA 1650 analyzer only.

Differences		
Item	New Device	Predicate
	Synchron CX4, Synchron CX5, Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira Plus systems. The Randox Laboratories Limited Liquid Protein Calibrators, should only be used by suitably qualified laboratory personnel under appropriate laboratory conditions. For in vitro diagnostic use.	
Calibrator level(s)	One level value for ASO and five level values for C3, C4, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, and Transferrin	The Bayer Predicate Device had one level value for C3, C4, IgA, IgG, IgM, Transferrin, Haptoglobin. The Randox Predicate Device had one level value for ASO, CRP, Ferritin, C3, C4, Prealbumin and five level values for IgA, IgG, IgM, Transferrin

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Not Applicable
   b. Linearity/assay reportable range:
      Not Applicable
   c. Traceability, Stability, Expected values (controls, calibrators, or methods):
      Traceability of the calibrators (except for ASO and Ferritin) was *via* the

reference material BCR Reference Material Proteins, CRM 470; NIBSC 94-572. The reference materials for ASO and Ferritin were '1st IRP AST91' and 'NIBSC 94/572' respectively.

Stability

The expiration date claim was 12 months.

Open vial stability - Data included control recovery from day 0, 7, 14, 21, 30. The results ranged from - 0.8% to 4.3% which were within the acceptable criteria of ± 5% versus fresh calibrators. On day 0 of the stability study, analytes are calibrated using a freshly opened vial calibrator set. (After the required volume is removed, vials are re-capped and stored at 2-8ºC). Data are recorded. The controls are then tested and controls must recover within their specified insert ranges for each analyte. On each subsequent time-points, the analytes are calibrated using previously stored open vial calibrators. Control recovery for those calibrated on open calibrator set must be within 5% to the recoveries of the control when calibrated on the freshly opened calibrator set.

Real time stability - Data included testing from day 0, 13, and 27 days at 37ºC compared to material stored at recommended temperature. The results were within the acceptance criteria of ≤ 5%. On day 0 of the real time stability study, sufficient volume of the calibrator sets (enough to cover all time points) are placed at three storage temperatures (+30º, 2-8º, -80 ºC). The +30 ºC stability is only assessed until week 8. At 4 and 8 week time-points a set of calibrators from each of the three stored temperatures is tested. Control recoveries are run and all control material must recover within the analyte specific ranges. After week 8, only the 2-8ºand -80 ºC calibrator sets are tested at weeks 8, 26, 30, 52, 56, 78, 90, 104, 108.

d. Detection limit:
Not Applicable.

e. Analytical specificity:
No Applicable.

f. Assay cut-off:
Not Applicable.

2. Comparison studies:
   a. Method comparison with predicate device:
   Not Applicable
   b. Matrix comparison:
   Not Applicable.
3. Clinical studies:
   a. Clinical sensitivity and specificity:
   Not Applicable
   b. Other clinical supportive data (when a is not applicable):
   Not Applicable.
4. Clinical cut-off**:**
   Not applicable

5. Expected values/Reference range:
   Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.